REMARKS

I. Prosecution History

A final Office Action issued on September 8, 2003. Applicants submitted a response thereto on October 6, 2003 within the three-month shortened statutory period. The Examiner issued an Advisory Action, mailed October 28, 2003, maintaining the final rejection of record. Applicants submit this supplemental response to the final Office Action and respectfully request the Examiner's consideration thereof.

It is believed that the claim amendments presented herein will advance the application to allowance.

II. Claim Amendments

Claim 1 has been amended to include the embodiment of original claim 19, now cancelled. Support is also provided at page 8, lines 19-20 of the specification. New claim 28 is directed to the preferred embodiment disclosed at page 8, lines 22-23 of the specification. The remaining claim amendments concern the amended dependency of claims 23-26 in view of the cancellation of claim 19 and introduction of new claim 28. Applicants submit that the claim amendments are fully supported by the specification as originally filed and, therefore, no new matter has been added.

Amended claim 1 clarifies that the modifying agent and water insoluble polymer are present in the claimed delayed release dosage form in a weight ratio of from 90:10 and 50:50. All of the remaining claims are dependent, either directly or indirectly, on claim 1. Accordingly, all of the pending claims are defined by the features of amended claim 1.

III. Claim Rejection – 35 U.S.C. §103(a)

Claims 1, 3-20 and 23-27 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Makino et al. (EP 0237 200) ("Makino") in view of Okada et al. (JP402237918) or US 5,776,489 to Preston et al.

Applicants rely on their arguments of record with respect to the prior art rejection. In addition, claim 1 has been amended to clarify that the modifying agent and water insoluble polymer are present in the claimed delayed release dosage form in a weight ratio of from 90:10 and 50:50. The recited ratio advantageously provides a formulation that is (1) acid resistant notwithstanding the absence of an enteric coat and (2) disruptable thereby providing a delayed release of the active ingredient.

In contrast, the primary reference to Makino uses significantly smaller amounts of modifying agent, e.g., talc, relative to the water insoluble polymer, e.g., Eudragit®. In this regard, the Examiner's attention is directed to Example 9 of Makino at pages 14-15 (104.7 mg Eudragit® vs. 9.6 mg talc). Thus, Makino neither discloses nor suggests the claimed invention and advantages, i.e., acid resistant notwithstanding the absence of an enteric coat and disruptable to provide a delayed release of the active ingredient.

The secondary references also do not appear to disclose or suggest the recited ratio of modifying agent and water insoluble polymer.

For all of the foregoing reasons, Applicants submit that the cited prior art, whether taken alone or in combination, does not suggest the claimed invention. Withdrawal of the §103 rejection is requested.

CONCLUSION

Applicants have made a good faith attempt to respond to the Office Action. It is respectfully submitted that claims 1, 3-18, 20 and 23-28 are in condition for allowance, which action is earnestly solicited.

Any fees due in connection with this response should be charged to Deposit Account No. 23-1703.

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Respectfully submitted,

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